Remarks

Claims 25-58 are pending in the instant application. Applicants have canceled claims 1-24 without prejudice or disclaimer. Applicants reserve the right to pursue the canceled subject matter in one or more continuing applications. Claims 27, 30-34, 39, 42-48, 51, and 54-58 have been withdrawn from consideration. Applicants have amended claims 35, 39, and 40. Claims 35 and 39 have been amended to correct a typographical error while claim 40 has been amended to delete a particular term. No new matter has been added.

I. Election Without Traverse

The Examiner has treated the Applicants' sequence election as an election without traverse "because Applicant has not stated otherwise." *See* Paper No. 7, page 2, line 9.

Applicants respectfully disagree with the Examiner in treating the election as an election without traverse. Applicants had indicated in their response entitled "Preliminary Amendment and Provisional Election With Traverse Under 37 C.F.R. 1.111" submitted July 16, 2003, that the provisional election to the claimed polypeptide sequence was made with traverse. *See* Paper No. 6, page 9 (emphasis added). Clearly, such a traversal extended to the entire restriction requirement articulated in Paper No. 5. Applicants respectfully request that the Examiner recognize the Applicants' election as such.

II. Separate and Distinct Inventions

The Examiner has determined Applicants' claims to be drawn to separate and distinct invention, "as they refer to heterologous polypeptides, polypeptides encoded by HNTBI57 cDNA contained in ATCC Deposit Number 209423, and to polypeptide sequences heterologous to SEQ ID NO:83. There are no claims in the original restriction election directed to these separate and distinct inventions." *See* Paper No. 7, page 2, lines 11-14.

Applicants respectfully disagree. Applicants' claims to heterologous polypeptides require the claim element of SEQ ID NO:466 – thus, it cannot be considered separate and distinct from SEQ ID NO:466 itself. Applicants further submit that the elected sequence, SEQ ID NO:466, comprise a genus of sequences, wherein a polypeptide sequence heterologous to SEQ ID NO:466 is a species of the genus. As such, Applicants

respectfully request the Examiner to rejoin claims 27, 39, and 51 upon the indication of allowable subject matter.

In addition, Applicants submit that polypeptides encoded by HNTBI57 cDNA contained in ATCC Deposit Number 209423 do not constitute a separate and distinct invention. A search of the SEQ ID NO:93 would yield the polypeptide encoded by SEQ ID NO:466 and the polypeptide encoded by the HNTBI57 cDNA contained in ATCC Deposit Number 209423. Hence, a polypeptide encoded by the HNTBI57 cDNA contained in ATCC Deposit Number 209423 corresponds to the polypeptide of SEQ ID NO:466. Accordingly, Applicants respectfully request reconsideration of the withdrawal of claims 30-34, 42-48 and 54-58 from consideration.

III. Rejection of Claims Under 35 U.S.C. §§ 101/112

The Examiner has rejected claims 25, 26, 28, 2, 35-38, 40, 41, 49, 50, 52, and 53 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific and/or substantial asserted utility or a well-established utility.

Applicants respectfully disagree and traverse.

In order to find that an asserted utility is neither specific nor substantial, the burden is on the Examiner to make a *prima facie* case showing that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the Applicant to be specific or substantial. *See* M.P.E.P. § 2107.02(IV); Utility Examination Guidelines, 66 FR 1092, January 5, 2001 at 1098, col. 3 (emphasis added). In the instant case, the Examiner has provided generalized statements that utilities asserted for the polypeptide SEQ ID NO:164 are not substantial because 1) the utilities asserted by Applicants are general utilities that would be applicable to a broad class of the invention; 2) the utilities asserted by Applicants requires further research to identify a "real world" use; and 3) one of ordinary skill in the art would not appreciate why the invention is useful based on the characteristics of the invention. Thus, while the Examiner has acknowledged that Applicants have asserted utilities in the specification, the utilities are dismissed as being insubstantial or non-specific.

The Examiner alleges that Applicants' asserted utilities are not specific since "the disclosed uses of these compositions are not specific and are generally applicable to any polypeptide." *See* Paper No. 7, page 4, lines 18-20. The test for specificity is whether an asserted utility is specific to the subject matter claimed, in contrast to a utility that would

be applicable to the broad class of the invention, such as use of a complex machine for landfill. *See*, for example, the Utility Examination Guidelines. The disclosed utilities for SEQ ID NO:466 discussed above are specific, in that not every protein is expressed primarily in fetal lung, stromal cells and lymphoma cells. *See* page 166, lines 8-9 of the specification as filed. Consequently, the skilled artisan would most certainly not consider such a use to be a "throw-away utility" such as landfill.

The Examiner further alleges that the claimed invention is not supported by a substantial utility. In particular, the Examiner alleges, "the research contemplated by Applicants to characterize potential protein products, especially their biological activity does not constitute a specific and substantial utility." Preliminarily, the Federal Circuit has found that, "Usefulness in patent law . . . necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995). Applicants assert that based on what is disclosed in the specification about SEQ ID NO:466, it would be reasonable to assert that the claimed invention is useful as a diagnostic marker for haematopoietic and respiratory disorders. Indeed, third party evidence provides corroborating evidence of Applicants' assertion as a diagnostic marker for hematopoietic disorders. *See* Reference A of IDS submitted July 16, 2003. The M.P.E.P. states, "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility. *See* M.P.E.P. § 2107.01(I). Applicants thus assert the claimed invention is supported by a substantial or "real world" utility.

Finally, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility. M.P.E.P. § 2107 at 2100-30 and 2100-40. The Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See Id.*; *see* also, *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995).

In view of the above arguments, Applicants have provided evidence and reasoning which supports the Applicants' assertion of utility. The utilities asserted in the

specification for Secreted Protein HNTBI57 (SEQ ID NO:466) are specific, substantial and credible. Accordingly, Applicants respectfully submit that the rejection of claims 35-38, 40, 41, 49, 50, 52, and 53 under 35 U.S.C. § 101 has been obviated. Therefore, Applicants respectfully request that the rejection be reconsidered and withdrawn.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

IV. Claim Rejections Under 35 U.S.C. §112, First Paragraph Written Description of Claims 35-38, 40, 41, 49, 50, 52, and 53

Claims 35-38, 40, 41, 49, 50, 52, and 53 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully disagree and traverse.

A. Variants (Claims 35-38, 40, and 41)

With respect to claims 35-38, 40 and 41, Applicants remind the Examiner that the test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil Co. v.*

Atlantic Richfield Co., 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), hereinafter referred to as "*Unocal.*" While the applicant must "blaze marks on trees," rather than "simply [provide] the public with a forest of trees," an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. *See also* M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."). The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. As the court noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added).

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by claims 35-38, 40 and 41 in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

The Federal Circuit has held in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997; hereinafter *Eli Lilly*) that a description of a genus of cDNAs may be achieved by reciting a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or by reciting structural features common to a substantial portion of the members of the genus. Therefore, it logically follows that claims to polypeptides encoded by cDNAs may also be satisfied by providing sequences of a representative number of polypeptides which fall within the scope of the genus *or* by providing a recitation of structural features common to a substantial portion of the members of the genus.

Applicants assert that, in the instant case, the second test set forth in *Eli Lilly* has been satisfied because Applicants' description of the reference polypeptide sequence, SEQ ID NO:466, provides one skilled in the art with the necessary structural features common to a substantial portion of the members of the genus. Applicants further point out that the recitation of the structural features of the reference protein is a recitation of the structural features common to the members of the claimed genus because the proteins included within the claimed genus will have at least 90% of the amino acids of their amino acid sequence primary structure in common to the reference polypeptide of SEQ ID NO:466.

Indeed, nothing more than a basic knowledge of the genetic code and what is described in the specification would be required for the skilled artisan to identify every single one of the polypeptides that are 90% identical to the amino acid sequence of SEQ ID NO:466 capable of generating or selecting an antibody that binds to SEQ ID NO:466. Clearly, such knowledge is well within what is expected of the skilled artisan. Therefore, in accord with *Eli Lilly,* the specification clearly conveys that Applicants were in possession of the claimed invention on the priority date of the instant application.

In view of the arguments above, Applicants submit that the claimed subject matter fully meets the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of claims 35-38, 40 and 41 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. New Matter (Claim 35)

The Examiner has rejected claim 35 as containing new matter since there is no support in the specification for this particular fragment as it relates to SEQ ID NO:466. Applicants have amended claim 35 to correct a typographical error. Applicants had incorrectly identified the full length sequence of SEQ ID NO:466 to be 190 amino acids, whereas the correct length of SEQ ID NO:466 is 341 amino acids. Support for this amendment can be found on page 206 of the sequence listing as filed. In light of this amendment, Applicants have obviated the Examiner's rejection and respectfully request the reconsideration and withdrawal of the rejection to claim 35.

C. 30 and 50 Contiguous Amino Acids (Claims 49-50 and 52-53)

The Examiner has requested Applicants to point out in the specification support for the fragments "at least 30 contiguous amino acids" and "at least 50 contiguous amino acids" in claims 49 and 50 respectively. Applicants direct the Examiner to pages 283-285 of the specification as filed, specifically page 284, lines 9-19, for support of the fragments recited in the claims. Applicants respectfully request that the Examiner's rejection to these claims be withdrawn.

V. Claim Rejections Under 35 U.S.C. §112, Second Paragraph

Claim 40 has been rejected under 35 USC 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as

the invention. In particular, the Examiner alleges, "Claim 40 is vague and indefinite as to what is meant therein by the limitation 'acceptable carrier'. This implies that the carrier be acceptable depending upon the intended use of the protein." *See* Paper No. 7, page 5, lines 7-9.

Applicants have amended claim 40 to delete the term "acceptable." Applicants believe that the claim as written complies with 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Conclusion

Applicants respectfully request the amendments and remarks of the present response be entered and made of record in the present application. In view of the foregoing amendment and remarks, Applicants believe they have fully addressed the Examiner's concerns and that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the allowance of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: DECEMBER 9, 2003

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